

## Society of Surgical Oncology: Statement on Genetic Testing for Cancer Susceptibility

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Recent and rapid advances in genetic technology have resulted in many difficult ethical and financial decisions. Because genetic testing and counseling is the direct purview of surgical oncologists, the Society for Surgical Oncology (SSO) endorses reform in four important areas in which genetic testing poses potential dilemmas and medical, financial or psychosocial risks: clinical patient care, medical education, research and patient rights or advocacy.

### I. CLINICAL PATIENT CARE

#### A. Use of Informed Consent

Informed consent before performing genetic testing is needed in order to make the individual aware of the risk of the disease, the risk of the procedure, and the accuracy of the testing and options. Informed consent will minimize false expectations on the part of the patient regarding either positive or negative results.

The informed consent process may include the following items:

- Options for risk estimation without genetic testing.
- Risk that the test will not accurately reflect the patient's genotype and/or risk for the disease.
- Explanation of the possibility that the test will not be informative.
- Risks of psychological distress and family disruption whether or not a mutation is found.
- Risks of insurance or employer discrimination.
- A Statement on Confidentiality to include those persons to whom results may be disclosed.
- Risk of passing a mutation to children.
- Risk for disease in spite of negative results.
- Options and limitations of medical surveillance and screening after testing, whether genetic testing is positive or negative.
- Information on the specific test being performed

and a statement that no test other than those authorized will be conducted.

- A statement about the potential use and disposal of the material.
- Fees involved in testing, genetic counseling, and follow-up.
- Signature of the individual to be tested or his/her representative.

#### B. Indications for Genetic Testing

The SSO recommends that genetic testing should be offered only when:

- The patient understands the advantages and liabilities of genetic testing.
- Families have a well-defined hereditary syndrome for which either a positive or negative result will change medical care, e.g., familial adenomatous or multiple endocrine neoplasia syndrome. Genetic testing is now considered standard in the care of such families.
- The proband has a strong family history of cancer or characteristics of hereditary cancers.
- The test can be adequately interpreted.
- Results will influence the medical management or quality of life of the patient or other family members. In certain hereditary syndromes, the medical benefit or identification of a genetic abnormality is presumed but not proven. Such information would, however, change surveillance patterns or prompt medical or surgical preventive options, e.g., Hereditary Non-Polyposis Colon Cancer, Hereditary Breast Ovarian Syndrome, or Li Fraumeni Syndrome. Genetic counseling can still be offered because people often have questions and misunderstandings about their individual risk.

#### C. Testing Facilities

Physicians should use laboratories for genetic

testing that are committed to the validation of the methodology used for testing and to facilitate the participation of families in studies that examine long-term outcomes.

#### **D. Counseling**

Patients and families who undergo genetic testing should receive pre- and posttest genetic counseling from a genetic counselor (who is certified or eligible for certification) and /or someone who is knowledgeable in genetics.

#### **E. Medical Management After Testing and Counseling**

The SSO endorses the development of guidelines regarding cancer screening that use radiographic, biochemical, endoscopic, and /or clinical criteria. The SSO strongly encourages the use of preventive, screening, and surveillance methods for early cancer detection in individuals with a predisposing gene for cancer. The use of these methods should be offered in the context of prospective clinical research trials.

### **II. MEDICAL EDUCATION**

The SSO supports programs in the following areas:

#### **A. Guideline Development**

Guidelines for genetic testing and genetic counseling should include the need for privacy in obtaining genetic information, surveillance, and prophylactic medical and/or surgical therapy.

#### **B. Continuing Medical Education (CME)**

CME accredited courses should be available to update physicians regarding the use of counseling, informed consent, and genetic testing in the "at risk" population. Such courses should teach physicians and appropriate personnel how to quantitatively assess and document cancer risk, educate the physician regarding genetic counseling before and after testing, delineate the benefits and limits of genetic tests, and inform patients of family support services. Such courses should include information on molecular genetics, pedigree construction, mathematical risk analysis, medico-legal implications of genetic testing, the availability of research trials, and resources for genetic evaluation and counseling.

#### **C. Resident Education**

The SSO endorses the incorporation of the above information and guidelines into the resident core curriculum.

#### **D. Patient Education**

The SSO will remain positive in developing guidelines for genetic testing that can be used by patients. The SSO will provide information regarding specimen collection and handling, interpretation of test results, participation in research studies, and the listing of qualified laboratory facilities. The SSO will continue as appropriate to educate the public about the opportunities for pre- and posttest counseling and on the availability of support groups. The SSO will also promote public education through the SSO home page and other venues where appropriate.

### **III. RESEARCH**

The benefits of genetic testing will not be realized and patients will not participate in clinical trials if they fear insurance or employment discrimination as a result of such testing.

#### **A. Long-Term Outcome Studies**

Genetic screening and intervention for cancer susceptibility should be performed in the setting of long-term outcome studies, as suggested by the National Advisory Council for Human Genome Research, the American Society of Human Genetics, and the American Society of Clinical Oncology. Genetic testing for individuals without a family history of cancer, or syndromes for which the medical benefits of the identification of a genetic abnormality are not apparent, should be limited to research studies. In well-defined genetic syndromes where identification of a genetic abnormality is of assumed, but not proven, benefit, clinical studies should be required to predict age-related risk and penetrance, and to document the effectiveness of screening, preventative treatment, surgical intervention, and counseling. Accordingly, screening programs should have a clearly defined purpose, be more than a laboratory test, approved by the appropriate institutional review board, and evaluated periodically to determine if such a program is meeting its goals. The SSO endorses physician and patient participation in clinical trials that evaluate the efficacy of surveillance regimens, prophylactic medical or surgical therapy, and counseling.

#### **B. National Cooperative Registry**

The SSO will continue to endorse, along with other organizations, the design and implementa-

tion of national cooperative registries that preserve confidentiality.

### C. Patient-Oriented Research

The SSO endorses research on the psychosocial implications of genetic testing of patients undergoing genetic counseling. Such research would assess the value of different strategies of support and counseling.

## IV. PATIENT ADVOCACY

Genetic testing raises a host of medical, legal, social, psychological, and ethical issues for patients and their families. Genetic information is information about genes, gene products, or inherited characteristics of a patient or family member. Maximizing the medical benefits of genome research will require a social environment in which health care consumers are protected from employment or insurance discrimination and from stigma based on their genetic variability.

Possible detrimental outcomes of genetic testing include:

- Genetic discrimination—denial of life insurance, health insurance, or access to schooling or jobs based on genetic mutations.
- Differential treatment—employers hire only those people whose genes indicate that they are resistant to illness or health hazards at work.
- Eugenics—social or political pressure applied to the individual to make childbearing decisions (choice of spouse, abortion of fetuses with genetic abnormalities, or individual sterilization) or withholding treatment for people with genetic disorders on the basis of genetic information.

### A. Regulative Legislation

The SSO endorses passage of state and federal legislation that contains the following key issues and encourages states to pass separate legislation on genetic testing to promote increased awareness:

1. *Strengthen Regulatory Authority Over Laboratories*
  - Oversight of the products used in genetic testing.
  - Inter-laboratory comparisons of reference samples and creation of laboratory standards.

- Quality assurance and control.

Federal policies, i.e. the Clinical Laboratory Improvement Act of 1988, should be updated to meet the standards for laboratory genetics services established by the American College of Medical Genetics.

2. *Prohibit Discrimination, Based on Genetic Information, by Insurance Companies or Employers*

The SSO endorses legislative efforts to prohibit group, as well as individual, insurance plans from requiring an applicant to disclose genetic information or from discriminating for the purposes of employment or health insurance. Insurance providers should be prohibited from using genetic information, or using an individual's request for genetic services, to (a) deny or limit any coverage, (b) establish eligibility for coverage, (c) enroll for coverage, (d) continue coverage, (e) require special contributions, or (e) establish differential rates or premium payments. The SSO supports legislation that allows the participation in research studies without fear of reprisal from health insurers or employers.

3. *Coverage of Services*

The SSO endorses legislation that mandates insurance and Medicare reimbursement for all items and services related to genetic testing for cancer, counseling, and preventive oncology if recommended by a qualified health care professional under the above set guidelines.

4. *Confidentiality—Genetic Privacy*

The SSO supports legislation that defines the rights of individuals whose DNA samples are collected, stored, and analyzed, as well as legislation that defines the rights of individuals whose genetic information is stored and disclosed. Proposed legislation should not impact on Clinical Trials or Research.

5. *The SSO endorses efforts to secure funding for a National Cooperative Registry*